

Exhibit 300: Capital Asset Plan and Business Case Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview (All Capital Assets)

1. Date of Submission: 2010-03-17 14:10:13

2. Agency: 009

3. Bureau: 10

4. Name of this Investment: FDA MedWatch Plus

5. Unique Project (Investment) Identifier: 009-10-01-03-01-0042-00

6. What kind of investment will this be in FY 2011?: Mixed Life Cycle

- Planning
- Full Acquisition
- Operations and Maintenance
- Mixed Life Cycle
- Multi-Agency Collaboration

7. What was the first budget year this investment was submitted to OMB? *

8. Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.

The FDA receives more than 600,000 voluntary post-marketing adverse event (AE) reports annually from manufacturers, health care professionals and consumers for all FDA-regulated products. The reports are analyzed by FDA safety evaluators for product risk assessment. Currently, a variety of computer programs enter the AE report into various databases that contain an archive of more than 3 million AE reports. Not all AE reports are submitted electronically, and there are many paper and data entry steps. Additionally, reviewers lack the most up-to-date signal detection technology in order to find patterns that could be buried in the massive amount of data being reviewed. The MedWatch Plus Investment will close the current performance gap to create a fully automated system that possesses up-to-date data with seamless integration points facilitating data sharing and more efficient reviews by the safety evaluators. This investment includes two system components, the MedWatch Plus Portal to receive and process AE reports, and the FDA Adverse Events Reporting System (FAERS) to allow for scientific and quantitative analysis of received reports. The MedWatch Plus Portal will institute a single Internet portal with a user-friendly electronic submission capability, encouraging the reporting of information in a quality and uniform manner. Behind the portal will be FAERS, a single agency-wide data warehouse of AE reports instead of various separate databases. This will enable data sharing through the seamless integration of data. FDA safety evaluators will possess the ability to make vital connections to AE data and strengthen risk detection by finding patterns in data. Medwatch Plus specifically aligns to the eGov PMA initiative. An outcome of this investment will be to reduce the average unit cost to prepare and process AE reports. It will also increase the consistency and timeliness of reports by utilizing standardized data collection processes. Moving towards an efficient fully electronic process, instituting a user-friendly website encouraging voluntary reports, consolidating the databases into a single data warehouse and developing powerful tools for risk detection aligns the MedWatch Plus investment with the FDA strategic goal of improving patient and consumer safety and also with the DHHS strategic objective of improving health care quality, safety, cost, and value.

- a. Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned) alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

9. Did the Agency's Executive/Investment Committee approve this request? *

a. If "yes," what was the date of this approval? *

10. Contact information of Program/Project Manager?

- Name: *
- Phone Number: *
- Email: *

11. What project management qualifications does the Project Manager have? (per FAC-P/PM)? *

- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):

| Financial management system name(s) | System acronym | Unique Project Identifier (UPI) number |
|-------------------------------------|----------------|--|
| * | * | * |

a. If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one): *

- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

Section B: Summary of Funding (Budget Authority for Capital Assets)

1.

| Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES (REPORTED IN MILLIONS) (Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions) | | | | | | | | | |
|--|-----------------|---------|---------|---------|-----------|-----------|-----------|-----------------|-------|
| | PY1 and earlier | PY 2009 | CY 2010 | BY 2011 | BY+1 2012 | BY+2 2013 | BY+3 2014 | BY+4 and beyond | Total |
| Planning: | * | * | * | * | * | * | * | * | * |
| Acquisition: | * | * | * | * | * | * | * | * | * |
| Subtotal Planning & Acquisition: | * | * | * | * | * | * | * | * | * |
| Operations & Maintenance: | * | * | * | * | * | * | * | * | * |
| Disposition Costs (optional): | * | * | * | * | * | * | * | * | * |
| SUBTOTAL: | * | * | * | * | * | * | * | * | * |
| Government FTE Costs should not be included in the amounts provided above. | | | | | | | | | |
| Government FTE Costs | * | * | * | * | * | * | * | * | * |
| Number of FTE represented by Costs: | * | * | * | * | * | * | * | * | * |
| TOTAL(including FTE costs) | * | * | * | * | * | * | * | * | * |

2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:

*

Section C: Acquisition/Contract Strategy (All Capital Assets)

1.

Table 1: Contracts/Task Orders Table

| Contract or Task Order Number | Type of Contract/Task Order (In accordance with FAR Part 16) | Has the contract been awarded (Y/N) | If so what is the date of the award? If not, what is the planned award date? | Start date of Contract/Task Order | End date of Contract/Task Order | Total Value of Contract/Task Order (M) | Is this an Interagency Acquisition? (Y/N) | Is it performance based? (Y/N) | Competitively awarded? (Y/N) | What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A) | Is EVM in the contract? (Y/N) |
|-------------------------------|--|-------------------------------------|--|-----------------------------------|---------------------------------|--|---|--------------------------------|------------------------------|--|-------------------------------|
| GST0008AJL061 | CPAF: Cost Plus Award Fee | Y | 2008-03-26 | 2008-04-01 | 2013-03-31 | \$39.6 | * | * | * | * | * |
| HHSF223200750663G | T&M: Time & Materials | Y | 2007-08-31 | 2007-09-01 | 2010-08-31 | \$5.1 | * | * | * | * | * |
| TBD | CPAF: Cost Plus Award Fee | Y | 2009-04-01 | 2009-04-01 | 2017-03-31 | \$10.8 | * | * | * | * | * |
| HHSF223200830059C | T&M: Time & Materials | Y | 2008-09-22 | 2008-10-01 | 2009-09-30 | \$2.5 | * | * | * | * | * |
| HHSF223200750548G | T&M: Time & Materials | Y | 2009-05-15 | 2009-06-01 | 2013-03-31 | \$0.9 | * | * | * | * | * |
| TBD | T&M: Time & Materials | Y | 2009-09-22 | 2009-10-01 | 2011-09-30 | \$3.4 | * | * | * | * | * |
| HHSF223200650718G | T&M: Time & Materials | Y | 2006-09-14 | 2006-09-14 | 2008-09-30 | \$0.2 | * | * | * | * | * |

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

*

3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements? *

a. If "yes," what is the date? *

Section D: Performance Information (All Capital Assets)

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|---------|----------------|
| 2008 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 45% | 55% | 55% |
| 2008 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$15 | \$13 | \$13 |
| 2008 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of voluntary reports received for fda regulated products submitted by subject matter professionals | 15,105 | 15,558 | 19,038 |
| 2008 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 51% | 53% | 53% |
| 2009 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 55% | 60% | 55% |
| 2009 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$13 | \$12.50 | \$13 |
| 2009 | S.O. 1.3 - | * | * | increase in the | 0 | 15,350 | 0 |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|---------|----------------|
| | Improve health care quality, safety, cost and value | | | total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | | | |
| 2009 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 0% | 55% | 0% |
| 2009 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 14 days | 14 days | 14 days |
| 2010 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 55% | 65% | tbd |
| 2010 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$13 | \$10.90 | tbd |
| 2010 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step | 0 | 15,558 | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|---------|----------------|
| | | | | paper process by voluntary reporters | | | |
| 2010 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 0% | 55% | tbd |
| 2010 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 14 days | 14 days | tbd |
| 2011 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 65% | 69% | tbd |
| 2011 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$10.90 | \$10.30 | tbd |
| 2011 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | 15,558 | 17,153 | tbd |
| 2011 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step | 55% | 56% | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|---------|----------------|
| | | | | rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | | | |
| 2011 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 14 days | 10 days | tbd |
| 2012 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 69% | 72% | tbd |
| 2012 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$10.30 | \$9.60 | tbd |
| 2012 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | 17,153 | 18,011 | tbd |
| 2012 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 56% | 65% | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|--------|----------------|
| 2012 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 10 days | 8 days | tbd |
| 2013 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 72% | 74% | tbd |
| 2013 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$9.60 | \$9.10 | tbd |
| 2013 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | 18,011 | 18,551 | tbd |
| 2013 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 65% | 66% | tbd |
| 2013 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 8 days | 6 days | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|--------|----------------|
| 2014 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 74% | 76% | tbd |
| 2014 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$9.10 | \$8.60 | tbd |
| 2014 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | 18,551 | 19,107 | tbd |
| 2014 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 66% | 67% | tbd |
| 2014 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 6 days | 6 days | tbd |
| 2015 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of all adverse event (ae) reports submitted electronically compared to all ae reports submitted | 76% | 78% | tbd |

Table 1: Performance Information Table

| Fiscal Year | Strategic Goal(s) Supported | Measurement Area | Measurement Grouping | Measurement Indicator | Baseline | Target | Actual Results |
|-------------|--|------------------|----------------------|---|----------|--------|----------------|
| 2015 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | reduce unit cost associated with turning a submitted adverse event report into a verified record in a database | \$8.60 | \$8.10 | tbd |
| 2015 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the total number of reports via the user friendly, web-based, single-step rational questionnaire vs. the number submitted via the multi-step paper process by voluntary reporters | 19,107 | 19,698 | tbd |
| 2015 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | increase in the percentage of reports via the user friendly, web-based, single-step rational questionnaire vs. the percentage submitted via the multi-step paper process by voluntary reporters | 67% | 68% | tbd |
| 2015 | S.O. 1.3 - Improve health care quality, safety, cost and value | * | * | average processing time will be reduced for converting a voluntary paper ae report into a verified/usable record in a database. | 6 days | 6 days | tbd |

Part II: Planning, Acquisition And Performance Information

Section A: Cost and Schedule Performance (All Capital Assets)

| 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | | | | | |
|--|--------------------|-------------------|--------------------|-------------------|-------------------------|------------------------|--------------------------|-------------------------|
| Description of Milestones | Planned Cost (\$M) | Actual Cost (\$M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| MW+ Program Mgmt Support (FY09 Funding) | \$2.5 | \$2.3 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| MW+ Program Mgmt Support (FY10 Funding) | \$1.6 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| MW+ Program Mgmt Support (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| MW+ Program Mgmt Support (FY12 Funding) | * | * | 2012-04-01 | | 2013-03-31 | | 0.00% | 0.00% |
| MW+ Program Mgmt FTE (FY09-12 Funding) | \$2.1 | \$0.8 | 2009-04-01 | 2009-04-01 | 2013-03-31 | | 37.93% | 37.10% |
| MW+ Program Mgmt FTE (FY09-14 Funding) | \$1.5 | \$0.2 | 2009-04-01 | 2009-04-01 | 2015-03-31 | | 15.28% | 14.90% |
| MW+ Hardware and Software (FY09 Funding) | \$4.2 | \$3.8 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| MW+ Hardware and Software (FY10 Funding) | \$1.0 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| MW+ Hardware and Software (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| MW+ Hardware and Software (FY12-14 Funding) | * | * | 2012-04-01 | | 2015-03-31 | | 0.00% | 0.00% |
| MW+ Design, Build, Test, Training, and Implementation of Release | \$3.9 | \$3.3 | 2009-04-01 | 2009-04-01 | 2010-05-01 | 2010-05-01 | 84.62% | 100.00% |

| 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | | | | | |
|--|--------------------|-------------------|--------------------|-------------------|-------------------------|------------------------|--------------------------|-------------------------|
| Description of Milestones | Planned Cost (\$M) | Actual Cost (\$M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| 1 | | | | | | | | |
| MW+ Reqs Analysis, Design, Build, Test, Training, and Implementation Release 2 (FY09 & 10 Funding) | \$7.5 | \$0.0 | 2010-03-01 | 2010-03-01 | 2010-11-01 | | 0.00% | 0.00% |
| MW+ Reqs Analysis, Design, Build, Test, Training, and Implementation of Release 3 | \$1.7 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-02-01 | | 0.00% | 0.00% |
| MW+ C&A and Security Activities (FY09 Funding) | \$0.2 | \$0.1 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| MW+ C&A and Security Activities (FY10 Funding) | \$0.2 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| MW+ C&A and Security Activities (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| MW+ C&A and Security Activities (FY12 Funding) | * | * | 2012-04-01 | | 2013-03-31 | | 0.00% | 0.00% |
| MW+ Operations and Maintenance (FY10 Funding) | \$0.8 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| MW+ Operations and Maintenance (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| MW+ Operations and Maintenance (FY12-14 Funding) | * | * | 2012-04-01 | | 2015-03-31 | | 0.00% | 0.00% |
| MW+ Legacy Systems O & M (FY09-14 Funding) | \$10.8 | \$1.6 | 2009-04-01 | 2009-04-01 | 2015-03-31 | | 15.28% | 14.90% |
| FAERS Program | \$2.8 | \$2.5 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |

| 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | | | | | |
|--|--------------------|-------------------|--------------------|-------------------|-------------------------|------------------------|--------------------------|-------------------------|
| Description of Milestones | Planned Cost (\$M) | Actual Cost (\$M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| Mgmt Support (FY09 Funding) | | | | | | | | |
| FAERS Program Mgmt Support (FY10 Funding) | \$1.4 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| FAERS Program Mgmt Support (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| FAERS Program Mgmt Support (FY12 Funding) | * | * | 2012-04-01 | | 2013-03-31 | | 0.00% | 0.00% |
| FAERS Program Mgmt FTE (FY09-12 Funding) | \$2.1 | \$0.8 | 2009-04-01 | 2009-04-01 | 2013-03-31 | | 37.93% | 37.10% |
| FAERS Program Mgmt FTE (FY09-14 Funding) | \$0.7 | \$0.1 | 2009-04-01 | 2009-04-01 | 2015-03-31 | | 15.28% | 14.90% |
| FAERS Hardware and Software (FY09 Funding) | \$4.7 | \$4.2 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| FAERS Hardware and Software (FY10 Funding) | \$0.9 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| FAERS Hardware and Software (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| FAERS Hardware and Software (FY12-14 Funding) | * | * | 2012-04-01 | | 2015-03-31 | | 0.00% | 0.00% |
| FAERS Design, Build, Test, Training, and Implementation of Release 1 | \$5.9 | \$5.4 | 2009-04-01 | 2009-04-01 | 2009-09-28 | 2009-09-28 | 91.67% | 100.00% |
| FAERS Reqs Analysis, Design, Build, Test, Training, and Implementation Release 2 | \$4.1 | \$0.3 | 2009-08-01 | 2009-08-01 | 2010-11-30 | | 6.25% | 6.25% |

| 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | | | | | |
|---|--------------------|-------------------|--------------------|-------------------|-------------------------|------------------------|--------------------------|-------------------------|
| Description of Milestones | Planned Cost (\$M) | Actual Cost (\$M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| (FY09-10 Funding) | | | | | | | | |
| FAERS Reqs Analysis, Design, Build, Test, Training, and Implementation of Release 3 (FY10 and 11 Funding) | \$12.2 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| FAERS C&A and Security Activities (FY09 Funding) | \$0.2 | \$0.1 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| FAERS C&A and Security Activities (FY10 Funding) | \$0.2 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| FAERS C&A and Security Activities (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| FAERS C&A and Security Activities (FY12 Funding) | * | * | 2012-04-01 | | 2013-03-31 | | 0.00% | 0.00% |
| FAERS Operations and Maintenance (FY09 Funding) | \$0.5 | \$0.5 | 2009-04-01 | 2009-04-01 | 2010-03-31 | 2010-03-31 | 91.67% | 100.00% |
| FAERS Operations and Maintenance (FY10 Funding) | \$0.8 | \$0.0 | 2010-04-01 | 2010-04-01 | 2011-03-31 | | 0.00% | 0.00% |
| FAERS Operations and Maintenance (FY11 Funding) | * | * | 2011-04-01 | | 2012-03-31 | | 0.00% | 0.00% |
| FAERS Operations and Maintenance (FY12-14 Funding) | * | * | 2012-04-01 | | 2015-03-31 | | 0.00% | 0.00% |
| Closed FY07-08 Milestones Summary - DME | \$10.7 | \$10.7 | 2007-11-01 | 2007-11-01 | 2009-03-31 | 2009-03-31 | 100.00% | 100.00% |

* - Indicates data is redacted.